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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,469	03/01/2004	Mark Deem	020979-001910US	2103

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EXAMINER	
EREZO, DARWIN P	
ART UNIT	**PAPER NUMBER**
3773	

MAIL DATE	DELIVERY MODE
10/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,469	DEEM ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-16,18-24,33-40 and 55-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-16, 18-24, 33-40 and 55-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/14/09 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 10-16, 18-24, 33-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,129,756 to Kugler et al. in view of US 2003/0236567 to Elliot, and in further view of US 2004/0193254 to Greenberg et al.

Kugler discloses a stent-graft device comprising at least one self-expandable member **10** (col. 10, ll. 48-49); at least one tubular graft member **40,41** coupled to the stent member, the tubular graft member having leg members **20,30** and coupled with a self-expandable iliac stent (shown in Fig. 2); wherein the leg members are fully capable of being removed from the main graft members; wherein the self-expandable stent member **10** has a proximal portion that is not attached to the graft member and acts as an anchoring member at any location along vascular system, including a location superior to the renal arteries branching from the abdominal aorta or a location inferior to the renal arteries branching form the abdominal aorta; wherein the stent is formed from a wire (thus joining the unattached portion of the stent to the attached portion of the stent).

Kugler is silent with regards to the device comprising a skirt graft member coupled to the stent member and the graft member, wherein the skirt member is

configured to contact the inner wall of an aortic aneurysm; and wherein the tubular graft member, once deployed, comprises a sinusoidal leg member.

However, Elliot discloses a similar stent-graft device for treating aneurysm, wherein the device has a skirt **18** that is configured to contact the inner wall of an aneurysm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kugler to have a skirt portion as disclosed by Elliot because the skirt provides a seal between the aneurysm and the device.

With regards to a sinusoidal leg member, it is noted that this configuration is well known in the art. For example, Greenberg discloses a branched stent device similar to that of Kugler, wherein the device comprises a sinusoidal leg member (see Figs. 8a-8d). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kugler to also have a sinusoidal leg member since the shape is taught to be well known in the art, as disclosed by Greenberg, and since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Furthermore, the leg members of Kugler are disclosed as having corrugated portions **25,35** that provide enhanced longitudinal flexibility for the leg members, which would make it easier for the modification to include a sinusoidal portion. It would also be obvious to modify both leg members to be sinusoidal instead of just one since it has been held that mere duplication of the essential working parts of a device involves only

routine skill in the art. *In re Harza*, 274 F.2d, 669, 124 USPQ 378 (CCPA 1960). Note that having two sinusoidal leg members would allow said leg members to intertwine.

6. Claims 2-7, 37, 55-58 and 60-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. in view of Elliot and Greenberg et al., as applied to the claims above, and in further view of US 6,168,621 to Vrba.

The modified device of Kugler discloses all the limitations of the claims except for the stent member comprising both a self-expanding stent member and a balloon-expandable stent member. However, Vrba discloses a stent having both a self-expanding stent member and a balloon expandable stent member. This configuration is provided to allow immediate expansion of the stent member upon release, which will aid in placement of the stent during release but prior to using a balloon (col. 2, lines 4-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent member of Kugler to include both self-expanding and balloon-expandable stent members because it would allow the stent member to expand immediately upon release to position the stent in the right location prior to the expansion of a balloon, which would fully expand the entire stent member.

Vrba further discloses that the self-expanding stent members and the balloon-expanding stent members can be arranged in alternating sequence (col. 2, lines 50-55); wherein the stent member is made of nitinol (col. 2, line 7).

Vrba is silent with regards to the stent member being formed from stainless steel or to how the self-expanding stent members or the balloon-expanding stent members are connected to each other. However, the examiner takes Official notice that the use

of stainless steel in medical devices, especially stents, are extremely well-known, and that connecting stent portions via welding, adhesive, soldering are also well-known in the art (as evidenced by US 5,843,176; col. 3, lines 49-57). Therefore, such modifications would be obvious to one of ordinary skill in the art. It is further noted that the common knowledge or well-known in the art statement is taken to be admitted prior art because the applicant failed to traverse the examiner's assertion of official notice.

Note that Vrba discloses a device that is formed to be a cylinder (see Fig. 6, the length of the device is cylindrical), wherein the cylinder is formed of alternating self-expanding members and balloon expandable members; wherein the entire length of the device is made of the expandable members (including the middle portion).

Though Vrba discloses the middle portion to be comprised of balloon-expandable members, it is noted that one of ordinary skill in the art would have found it obvious to rearrange the members to have the self-expanding members be located in the middle portion since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Note that the balloon expandable members is fully capable of being expanded to a larger diameter than the self-expanding members since the diameter of the balloon expandable members would merely be dependent upon the inflation size of the balloon.

It is further noted that the arrangement taught by Vrba is disclosed to be "laminated" together since they are "composed of layers firmly united materials" (as defined by Merriam-Webster online dictionary: www.m-w.com"). Note that the applicant's specification does not clearly teach how the portions are laminated together.

7. Claims 8 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. in view of Elliot, Greenberg et al. and Vrba, as applied to the rejections above, and in further view of US 6,945,994 to Austin et al.

The modified device of Kugler discloses all the limitation of the claim except for the stent member having diamond-shaped members. However, Austin discloses a similar type of stent as Vrba, wherein the stent has both self-expanding and balloon-expandable stent members, and wherein the stent can have diamond-shaped, rectangular or even square patterns (col. 5, line 62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Kugler to include diamond-shaped stent members because Austin discloses that it is well known in the art for stents to have various shapes, including diamond-shapes.

Response to Arguments

8. Applicant's arguments with respect to claims 1-8, 10-16, 18-24, 33-40 and 55-73 in the reply filed on 8/14/09 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773